JUN 30 2010

510(k) Summary

The following 510(k) summary is being submitted as required by 21 CFR Part 807.92:

Date: 02/08/10

1. **Submission information:**

a) Submitter

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b) U.S Agent/Contact Person
13340 E Firestone Blvd. Suite J,
Santa Fe Springs, CA 90670
Priscilla Juhee Chung
Phone: 562-404-8466 Fax: 562-404-2757
Email : agent.fda@gmail.com

2. **Device Identification:**
Trade Name: Tyche® Pedicle Screw System
Common Name: Pedicle screw spinal system
Classification Name: Orthosis, Spondyloisthesis Spinal Fixation (21CFR880.3070, Product code MNH, MNI)

3. **Substantially Equivalent Predicate Legally Marketed Devices:**
The subject Tyche® Pedicle Screw System is substantially equivalent in function, design, composition, labeling, and intended use to:
OPTIMA™ Spinal System - K024096
4CIS® SOLAR SPINE SYSTEM - K082453
The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the above listed predicate devices.

4. **Description:**
The Tyche® Pedicle Screw System is made up of muti-axial and standard screws, rods, locking cap, adjustable cross connectors. This system's design is intended to stabilize the

spinal operative site during the fusion process of a bone graft in the disc space. All components are made from medical grade titanium alloy (Ti-6Al-4V-ELI) by such as ASTM F136. The products are supplied clean and "NON STERILE".

5. Indications for Use:

The Tyche® Pedicle Screw System is a non-cervical, pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S 1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, The Tyche® Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

6. Statement of Technological comparison:

The Tyche® Pedicle Screw System is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles. Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate devices and is safe and effective when used as intended.

7. Performance Date:

Bench testing (static and dynamic axial compression bending test and static torsion test of the worst case Tyche® pedicle screw system structure) as listed in section 2 (appendix III-brochure and IV-mechanical testing report) was performed in accordance with ASTM F 1717-04-Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 30 2010

Kyungwon Medical Co., LTD.
% Kodent Inc.
Ms. Priscilla Juhee Chung
13340 E Firestone Boulevard, Suite J
Sante Fe Springs, California 90670

Re: K100373
Trade/Device Name: Tyche® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 23, 2010
Received: June 24, 2010

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore, market the device subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100373

Device Name: Tyche® Pedicle Screw System

Indications For Use:

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Bechtold for

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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